



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/532,567  | 04/22/2005  | Stefano Donadio      | 892,280-553         | 6732             |
| 28523   | 7590        | 09/15/2009           | EXAMINER            |                  |
| PFIZER INC.<br>PATENT DEPARTMENT<br>Bld 114 M/S 114<br>EASTERN POINT ROAD<br>GROTON, CT 06340 |             |                      | KAM, CHIH MIN       |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1656                |                  |
|   |             |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|   |             |                      | 09/15/2009          | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/532,567 | <b>Applicant(s)</b><br>DONADIO ET AL. |  |
|                              | <b>Examiner</b><br>CHIH-MIN KAM      | <b>Art Unit</b><br>1656               |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15, 17, 18, 21 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) 3-9 and 11-13 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30 is/are allowed.
- 6) ☒ Claim(s) 2, 10, 14 and 21 is/are rejected.
- 7) ☒ Claim(s) 1, 2, 15, 17, 18 and 31-33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 April 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/27/05</u> .   | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1656

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I, claims 1-15, 17, 18 and 21 in the response to restriction requirement and amendment filed June 23, 2009 is acknowledged. Applicants further elect the amino acid sequence of SEQ ID NO:21 and the corresponding *dbv* ORF 20, and indicate that this is species election, and that upon the allowance of a generic claim, applicants are entitled to consideration of claims to additional species which depend from or otherwise required all the limitations of an allowable generic claim. Applicants' response has been considered, however, the arguments are not persuasive. As indicated in the restriction requirement (see page 3, line 17 to page 4, line 2), the election of a single amino acid sequence and the corresponding *dbv* ORF is not species election, but rather an election of distinct invention, because each polypeptide (SEQ ID NO:2-37 OR 38), which contains different amino acid sequence and has different function, is patentably distinct from each other. In the amendment, claims 24, 25, 27 and 28 have been cancelled, and new claims 30-33 have been added. Thus, claims 1-15, 17, 18, 21 and 30-33 are pending. Claims 3-9 and 11-13 are non-elected inventions and are withdrawn from consideration. Therefore, claims 1, 2, 10, 14, 15, 17, 18, 21 and 30-33 are examined.

### ***Abstract***

2. The abstract of the disclosure is objected to because it cites legal phrase such as "said", which should be avoided. Correction is required. See MPEP § 608.01(b).

### ***Informalities***

The disclosure is objected to because of the following informalities:

Art Unit: 1656

3. The specification cites embedded hyperlinks and/or other forms of browser-executable code (e.g., page 27, lines 17-18), which are impermissible and require deletion. Appropriate correction is required.
4. In the preliminary amendment filed April 22, 2005, a set of drawings (Figs. 1 and 2) were indicated to be submitted, however, there are no drawings found in the file. Please resubmit the drawings.

***Claim Objections***

5. Claims 1, 2, 15, 17, 18 and 31-33 are objected to because the claim contains recitation of non-elected sequences such as SEQ ID NO: 2-20 and 22-38.
6. Claim 2 is objected to because the claim recites items c), f), g) and h), not items a), b), c) and d). Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 2, 10, 14 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2, 10, 14 and 21 are directed to an isolated nucleic acid, wherein the nucleotide sequence is selected from the group consisting of: the nucleotide sequence of *dbv* ORF 20 (item

Art Unit: 1656

c), a nucleotide sequence encoding the same polypeptide encoded by *dbv* ORF 20 (item f), and a nucleotide sequence encoding a polypeptide that is at least 80% identical in amino acid sequence to a polypeptide encoded by *dbv* ORF 20 (item g; claim 2); the nucleic acid sequence comprising a nucleotide sequence that encodes a polypeptide required for the attachment of the mannosyl residue of A40926 consisting of *dbv* ORF 20 or other nucleotide sequences encoding the same polypeptide (claim 10); the nucleic acid sequence comprising a nucleotide sequence comprising the *dbv* gene cluster with a frame deletion in the nucleotide sequence encoding the polypeptide requirement for the attachment of the mannosyl residue (claim 14); or a method for increasing production of A40926 by a microorganism, comprising transforming with a recombinant DNA vector a microorganism that produces A40926 or a A40926 precursor by means of a biosynthetic pathway, wherein the DNA vector codes for the expression of an activity that is rate limiting in the pathway, and culturing the microorganism under conditions suitable for cell growth, expression of the gene, and production of the antibiotic or antibiotic precursor (claim 21).

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or

Art Unit: 1656

by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

While the specification discloses the present invention provides an isolated nucleic acid comprising a nucleotide sequence selected from the group consisting of: the *dbv* gene cluster (SEQ ID NO:1) encoding the polypeptide required for the synthesis of A40926 (item a), a nucleotide sequence encoding the same polypeptide encoded by the *dbv* gene cluster other than the nucleotide sequence of the *dbv* gene cluster (item b), a nucleotide sequence of *dbv* ORFs 1-37 encoding the polypeptide of SEQ ID NOs:2-38 (item c), and a nucleotide sequence encoding the same polypeptide encoded by the *dbv* ORFs 1-37 other than the nucleotide sequence of the ORF (item d); a nucleic acid comprising a nucleotide sequence encoding the ORF 20 polypeptide (SEQ ID NO:21) which is useful for the attachment of mannosyl residues to the core structure of a glycopeptides antibiotic precursor; and a method of increasing the production of A40926 by transforming a recombinant DNA vector a microorganism that produces A40926 by means of a biosynthetic pathway, where the vector comprises a DNA sequence chosen from any of ORFs 1 through 37 that codes for an activity that is rate limiting in the pathway (page 5, line 11-page 10, line 3), the specification does not disclose a genus of variants for nucleotide sequences encoding a polypeptide that is at least 80% identical in amino acid sequence to a polypeptide encoded by *dbv* ORF 20. Furthermore, the specification does not provide structure-function/activity correlation for polypeptide variants that are related to the polypeptide encoded by *dbv* ORF 20.

Art Unit: 1656

The specification does not provide sufficient guidance as to what structural differences are permissible in the nucleic acid variant that would still produce a functional protein related to the polypeptide encoded by *dbv* ORF 20. While the specification indicates the microorganism that produces A40926 by means a biosynthetic pathway is transformed with a recombinant DNA vector comprising a DNA sequence chosen from ORF1 through 37 (SEQ ID NO: 2 through 38), that codes for an activity that is rate limiting in the pathway, it does not provide an adequate written description for the whole genus of DNA sequences that code for an activity that is rate limiting in the pathway without indicating any structure, since the whole genus of DNA sequences would encompass substantial variations when only activity is cited. Furthermore, there is no sufficient description on structure to function/activity relationship in the disclosed nucleotide variants. Without guidance for structure to function/activity for polypeptide variants, one skilled in the art could not predict which portions of the sequence (structure) are essential to produce a functional polypeptide. Given the lack of a structure to function/activity relationship and lack of representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would not recognize Applicants were in possession of the claimed invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1656

8. Claims 2, 10 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 2 and 10 are indefinite because the claim does not further limit the independent claim, claim 1. Claim 1 encompasses the nucleotide sequence of *dbv* ORF 20 encoding the polypeptide of SEQ ID NO:21 (item c), or a nucleotide sequence other than *dbv* ORF 20 encoding the same polypeptide (item d), while claim 2 encompasses a nucleotide sequence encoding a polypeptide that is at least 80% identical in amino acid sequence to a polypeptide encoded by *dbv* ORF 20, which is not encompassed by claim 1. Claim 10 is included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which it depends.

10. Claim 14 is indefinite because the claim does not further limit the independent claim, claim 1. Claim 1 encompasses the *dbv* gene cluster (SEQ ID NO:1) encoding the polypeptide required for the synthesis of A40926 (item a), or a nucleotide sequence encoding the same polypeptide encoded by the *dbv* gene cluster (item b), while claim 14 encompasses a nucleotide sequence comprising the *dbv* gene cluster with a frame deletion in the nucleotide sequence encoding the polypeptide requirement for the attachment of the mannosyl residue, which is not encompassed by claim 1.



Art Unit: 1656

***Conclusion***

11. Claims 2, 10, 14 and 21 are rejected; and claims 1, 2, 15, 17, 18 and 31-33 are objected to. It appears that claim 30 is free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

August 18, 2009